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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,797	10/01/1999	STEVE A. HERWECK	ATA-257	8813

959 7590 03/24/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application N .	Applicant(s)	
	09/411,797	HERWECK ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-49 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-27,44 and 50-52 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant refers to "microporous portion" in line 2 of both claims 19 and 20. It is unclear whether Applicant is referring to the first microporous portion or the second microporous portion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-27, 44 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Maguire et al., 6,500,174.

As to claims 1, 6-9, 13, 14, 25 and 50, Maguire et al. discloses a member (210) constructed of a biocompatible material, the member having a longitudinal axis and a

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wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes (1202) interconnected by fibrils (1204), the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration, wherein the wall of the member includes at least one microporous portion of micro-channels (1206) formed by microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through micro-channels substantially controlling the permeation of fluid through the wall, see column 28, lines 3-17, and see Figure 12B.

As to claim 2, the material is ePTFE, see column 28, lines 3-5.

As to claim 4, the member has a hydrophobic exterior surface, see column 10, lines 9-14.

As to claim 10, the size of the micro-channels varies circumferentially, see Figure 12B.

As to claim 11, the member deploys to the second configuration upon application of a fluid having a pressure of approximately 1 psi to 250 psi.

As to claim 12, porosity is sufficient to allow fluid to pass therethrough at a flow rate of approximately 0.01 ml/min to 100 ml/min, see column 28, lines 15-17.

As to claim 15, the medicinal agent is antibiotics, see column 18, lines 16 - 25.

As to claim 16, the microporous portion of the wall borders a second portion of the wall that is generally impermeable, see column 27, lines 21-27, and lines 51-53.

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As to claims 17, the wall further includes a second microporous portion (i.e., a distal part of member 210) having a porosity sufficient for the fluid to permeate through the wall.

As to claim 19, the second microporous portion is considered to be spaced apart longitudinally from a first microporous portion (i.e., a proximal part of member 210).

As to claim 20, the second microporous portion (i.e., one side of member 210) is considered to be spaced circumferentially from a first microporous portion (i.e., the other side of member 210).

As to claim 27, the size of the micro-channels varies circumferentially about the member, see Figure 12B.

As to claim 44, the nodes (1202) are substantially perpendicular to the longitudinal axis of the balloon, see Figure 12B.

As to claim 18, an impermeable portion of the wall (i.e., at a node 1202) is considered interposed between the microporous portion and the second microporous portion.

As to claim 24, the microporous portion is considered to have a hydraulic conductivity less than the hydraulic conductivity of the body vessel.

As to claim 45, a first layer of biocompatible material is disclosed at (2) And a second layer of biocompatible material is disclosed at (11).

As to claims 25-27 and 44, the member is constructed of fluoropolymer material, see column 28, line 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 21-23, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al., 6,500,174.

Maguire et al discloses the invention substantially as claimed, see above, except for the specific internodal distance, nor the hydraulic conductivity as claimed.

However, Maguire et al. does teach that any of a number of different pore sizes may be appropriate depending on the particular application, see column 28, lines 15-17. Thus, it would have been obvious to modify the Maguire device to have an internodal distance or hydraulic conductivity as claimed by Applicant depending on the particular application as taught by Maguire.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 45-49 are allowed.

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Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L. 
March 23, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700